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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/654,543	09/02/2003	Charanpreet S. Bagga	OVIT-0252	3970

23377 7590 10/14/2008
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EXAMINER

PHILOGENE, PEDRO

ART UNIT	PAPER NUMBER
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3733

MAIL DATE	DELIVERY MODE
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10/14/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/654,543	Applicant(s) BAGGA ET AL.	
	Examiner Pedro Philogene	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 July 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 56-60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 56-60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-2, 9, 56-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reiley et al. (7,081,122) in view of Kriesell (2001/0025157).

With respect to the above claims, Reiley et al disclose kit for delivery of a composition into an intraosseous space comprising at least one cannula (50) at least one stylet (23) insertable into a cannula and being movable therein, at least one catheter (130) that is insertable into the cannula; and a system (136,140,142) for delivery of aliquots of the composition into the intraosseous space via the catheter; as set forth in column 4, lines 14-25, column 7, lines 39-59, column 8, lines 35-67, column 9, lines 1-67, column 10, lines 1-14.

It is noted that Reiley et al did not teach of a catheter having a substantially rigid high-porosity tip; as claimed by applicant. However, in a similar art, Kriesell, page 5, para [0086-0087] provides the evidence of the use of a catheter having a substantially high-porosity tip to permit the medicinal fluid to flow uniformly outward of the tip or for the predictable result of delivering the medicinal fluid.

Therefore, given the teaching of Kriesell, it would have been obvious to one having ordinary skill in the art at the time the invention to modify the tip of the catheter of

Art Unit: 3733

Reiley et al, as taught by Kriesell to permit the medicinal fluid to flow uniformly outward of the tip or for the predictable result of delivering the medicinal fluid..

It is noted that combination did not teach of a porosity about 60% to 905; as claimed by applicant. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to reach these workable percentages, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617F.2d 272, 205 USPQ 215 (CCPA 1980).

Claims 3-8, are rejected under 35 U.S.C. 103(a) as being unpatentable over Reiley et al. (7,081,122) in view of Kriesell (2001/0025157) in view of Moaddeb (6,671,561).

It is noted that the above combination of references did not teach of a tip made of a polylactic acid, and a tip partially coated with non-porous or semi-porous material, the material is a ceramic polymer or metal, the material is calcium phosphate, or titanium, the material is biocompatible or resorbable, the tip is biocompatible or resorbable, as claimed by applicant. However, in similar art, Moaddeb, column 4, lines 41-67, column 5, lines 1-8, provides the evidences the use of a porous layer tip including such material to allow the tip to be maneuvered more easily and safely into position with less patient trauma.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the material for the tip as taught by Moaddeb to allow the tip to be maneuvered more easily and safely into position with less patient

Art Unit: 3733

trauma, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Lashin, 125 USPQ 416.

Response to Amendment

Applicant's arguments filed 7/9/08 have been fully considered but they are not persuasive. Applicant stated "The "porous delivery tip" of the Kriesell publication is therefore adapted for use in connection with a delivery of a "small volume" of medicament at an "ultra low controlled flow rate". In clear contrast, the tool system of the Reiley patent requires the ability to dispense comparatively large volume of bone material in a sufficient brief period of time as to minimize the duration of the invasive surgical procedure". Therefore, the combination would have been unsatisfactory for the intended purpose. The examiner begs to differ. Contrary to applicant's argument, the combination is perfectly satisfactory, since the intended use of both references is to deliver a material. As to the flow rate or duration of the procedure, it all depends on the material and/or quantity to be delivered. If the quantity to be delivered and the space to be filled are small, it does not matter what the rate of delivery, the space would be filled at no time. Furthermore, in para[0104] Kriesell discloses "In certain instances, rate control frit may never be required" therefore using the device of Kriesell to deliver a large volume of bone restorative material in a sufficient brief period of time as to minimize the duration of the invasive surgical procedure. As to the percentage of porosity, see the action above.

Art Unit: 3733

As to the applicant's arguments that the reference to Moaddeb did not teach of a porous tip comprising polylactic acid, applicant's attention is directed to column 3, lines 48, Where Moaddeb discloses that the porous tip is made of polylactic acid. Therefore, combining the reference of Moaddeb with the references of Reiley/Kriesell would have been obvious to one of ordinary skill in the art. Since the device would be coated with the non-porous or semi-porous material, it infers that the coating would control the direction of flow of the composition.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pedro Philogene whose telephone number is (571) 272-4716. The examiner can normally be reached on Monday to Friday 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272 - 4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3733

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Pedro Philogene/
Primary Examiner, Art Unit 3733
October 10, 2008